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(54) **PARTIAL ENCAPSULATION OF STENTS**
TEILEINKAPSELUNG VON STENTS
ENCAPSULATION PARTIELLE D'ENDOPROTHESES

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(56) References cited:
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Description

1. Field of the Invention

[0001] The present invention relates generally to the field of medical devices, and more particularly, to encapsulation of stents.

2. Description of Related Art

[0002] Stents and related endoluminal devices are currently used by medical practitioners to treat portions of the vascular system that become so narrowed that blood flow is restricted. Stents are tubular structures, usually of metal, which are radially expandable to hold a narrowed blood vessel in an open configuration. Such narrowing (stenosis) occurs, for example, as a result of the disease process known as arteriosclerosis. Angioplasty of a coronary artery to correct arteriosclerosis may stimulate excess tissue proliferation which then blocks (restenosis) the newly reopened vessel. While stents are most often used to "prop open" blood vessels, they. can also be used to reinforce collapsed or narrowed tubular structures in the respiratory system, the reproductive system, biliary ducts or any other tubular body structure. However, stents are generally mesh-like so that endothelial and other cells can grow through the openings resulting in restenosis of the vessel.

[0003] Polytetrafluoroethylene (PTFE) has proven unusually advantageous as a material from which to fabricate blood vessel grafts or prostheses used to replace damaged or diseased vessels. This is partially because PTFE is extremely biocompatible causing little or no immunogenic reaction when placed within the human body. This is also because in its preferred form, *expanded* PTFE (ePTFE), the material is light and porous and is potentially colonized by living cells becoming a permanent part of the body. The process of making ePTFE of vascular graft grade is well known to one of ordinary skill in the art. Suffice it to say that the critical step in this process is the *expansion* of PTFE into ePTFE following extrusion from a paste of crystalline PTFE particles. Expansion represents a controlled longitudinal stretching in which the PTFE is stretched up to several hundred percent of its original length. During the expansion process fibrils of PTFE are drawn out of aggregated PTFE particle (nodes), thereby creating a porous structure.

[0004] If stents could be enclosed in ePTFE, cellular infiltration could be limited, hopefully preventing or limiting restenosis. Early attempts to produce a stent enshrouded with ePTFE focused around use of adhesives or physical attachment such as suturing (see for example U.S. Patent No. 5,405,377 to Cragg). However, such methods are far from ideal, and suturing, in particular, is very labor intensive. More recently, methods have been developed for encapsulating a stent between two tubular ePTFE members whereby the ePTFE of one-member contacts and bonds to the ePTFE of the other member through the openings in the stent. These methods are disclosed in recent publications WO 98/38947 and WO 96/28115. However, such a monolithically encapsulated stent tends to be rather inflexible. In particular, radial expansion of the stent may stress and tear the ePTFE. There is a continuing need for a stent that is encapsulated to prevent cellular intrusion and to provide a smooth inner surface blood flow and yet still capable of expansion without tearing or delaminating and is relatively more flexible.

SUMMARY OF THE INVENTION

[0005] The present invention is directed to encapsulated stents wherein flexibility of the stent is retained, despite encapsulation.

[0006] It is an object of this invention to provide a stent device that has improved flexibility, yet maintains its shape upon expansion.

[0007] It is also an object of this invention to provide a stent encapsulated to prevent cellular infiltration wherein portions of the stent can move during radial expansion without stressing or tearing the encapsulating material.

[0008] These and additional objects are accomplished by an encapsulation process that leaves portions of the stent free to move during expansion without damaging the ePTFE covering. The most basic form of this invention is produced by placing a stent over an inner ePTFE member (e.g., supported on a mandrel) and then covering the outer surface of the stent with an outer ePTFE tube into which slits have been cut. The outer ePTFE tube is then laminated to the inner ePTFE through openings in the stent structure to capture the stent. By selecting the size and location of the slits it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. Not only does the slit prevent capture of the underlying PTFE, it forms a focal point for the PTFE to flex. A more complex form of the process is to place over the stent an ePTFE sleeve into which apertures have been cut. This "lacey" outer sleeve leaves portions of the stent exposed for increased flexibility and for movement of the stent portions during expansion without damaging the ePTFE. Although a single stent can be used, these approaches lend themselves to use of a plurality of individual ring stents spaced apart along an inner ePTFE tube and covered by a "lacey" ePTFE sleeve.

[0009] In the present invention, individual ring stents are partially encapsulated using the procedure outlined above. Preferably, ring stents of zigzag sinusoidal structure are placed "in phase" (e.g., peaks and valleys of one stent aligned with those of a neighboring stent) on the surface of a tubular ePTFE graft supported by a mandrel. A sleeve of ePTFE is cut using CO_2 laser so that openings are created, resulting in a "lacey" pattern. This "lacey" sleeve is then placed over the ring stents. The resulting structure is then subjected to heat and

pressure so that regions of ePTFE become laminated or fused together where the lacey sleeve contacts the tubular graft. In addition, the ends of the stent can be completely encapsulated, by known methods, to stabilize the overall structure.

[0010] A more complete understanding of the encapsulation process will be afforded to those skilled in the art, as well as a realization of additional advantages and objects thereof, by a consideration of the following detailed description of the preferred embodiment. Reference will be made to the appended sheets of drawings which will first be described briefly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

Fig. 1 is a perspective view of a tubular ePTFE member with individual ring stents arranged thereon.

Fig. 2 is a perspective view of the "lacey" sleeve of the present invention.

Fig. 3 is a perspective view of the sleeve in Fig. 2 placed over the structure of Fig. 1.

Fig. 4 is a perspective view of one configuration of the slitted sleeve of the present invention with longitudinally oriented slits.

Fig. 5 is a perspective view of a second configuration of the slitted sleeve of the present invention with circumferentially oriented slits.

Fig. 6 is a perspective view of a third configuration of the slitted sleeve as it is placed over the structure in Fig. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0012] The present invention satisfies the need for an encapsulated stent device to prevent restenosis that is flexible upon expansion and contraction so that the general structural form is retained. This is accomplished encapsulating a stent or a plurality of stent rings using an ePTFE covering into which openings have been cut.

[0013] Referring now to the drawings, in which like reference numbers represent similar or identical structures throughout, Fig. 1 illustrates an initial step in constructing the partially encapsulated stent of the present invention. A tubular ePTFE graft **20** is placed over a mandrel for the assembly of a device **10** (Fig. 3). A stent is then placed over the graft **20**. In a preferred embodiment, as shown in Fig. 1, a series of zigzag sinusoidal ring stents **30** are placed over the outer surface of the graft **20**. Alternatively, one or more stents wherein each stent comprises more than one ring or hoop (e.g., where the rings are helically connected) can be used. The ring stents **30** can be made of any material but a preferred material is metal. The zigzag ring stents **30** may be assembled "in phase" with each adjacent ring stent having peaks and valleys aligned. Alternatively, the individual stents **30** can be "out of phase" to different degrees. It will be apparent that the phase relation of adjacent stents **30** will alter the lateral flexibility as well as the longitudinal compressibility of the structure. The phase relationship can be varied along the length of the device **10**, thereby altering the physical properties in different portions of the device **10**. Having individual ring stents **30**, as opposed to a single tubular stent, provides the advantage that the periodicity, or the number and precise shape of the zigzags per ring, can readily be varied along the length of the graft to influence flexibility and stability properties of the structure. Also, spacing of the individual stents (number of stents per unit length) as well as the phase relationship of stent to stent can be varied to produce stent grafts with desired properties. By placing the ring stents **30** over the outer surface of the tubular ePTFE graft **20**, the resulting structure has an inner (luminal) surface that is completely smooth to facilitate the flow of blood. However, there may be instances where the ring stents **30** or other tubular stents are advantageously placed in contact with the inner graft surface or on both the inner and outer surfaces, as one of ordinary skill in the art will readily appreciate.

[0014] Fig. 2 shows the structure of a "lacey" graft **40** comprising a sleeve of ePTFE **42** into which apertures have been cut. This "lacey" graft **40** is placed over the ring stents **30** in the preferred embodiment. The "lacey" graft **40** is created by cutting openings **44** in a tubular ePTFE sleeve **42**. The openings **44** were cut into the sleeve by a CO_2 laser, although any other cutting technology could readily be employed. The "lacey" graft **40** is slid over the ring stents **30** and the underlying tubular graft **20** to form the preferred device **10** shown in Fig. 3. The device **10** is then exposed to heat and pressure, such as that caused by wrapping with PTFE tape followed by heating in an oven, thereby causing the ePTFE regions of the "lacey" graft **40** to fuse or laminate to the tubular graft **20** wherever they touch each other. It should be appreciated that the circumferential sections of ePTFE **46** that are placed over the ring stents **30** can encompass many different designs. As illustrated, a sleeve **42** with openings **44** cut out is one way of accomplishing the goal of flexibility and stability. The openings **44** between the circumferential sections of ePTFE **46** can be altered to control the degree of flexibility and stability desired. In the preferred embodiment shown in Fig. 3, the "lacey" graft **40** forms a number of circumferential sections **46**, which are intended to cover a portion of the circumference of each ring stent **30**, leaving the ends of the zigzags uncovered. By circumferentially covering only a portion of each ring stent **30**, the maximum amount of lateral flexibility is provided.

[0015] However, circumferentially covering the individual ring stents **30** without any longitudinal support would result in a structure with little longitudinal strength and stability that would be prone to "telescoping". Thus, the longitudinal sections **48** that connect the circumfer-

ential sections of ePTFE **46** are important, because the longitudinal sections **48** are completely laminated to the underlying graft **20** and act as "anti-compression" devices by resisting the shortening of the structure **10** (the double thickness of ePTFE resists telescoping of the longitudinal sections **48**). The width of the circumferential sections **46** and the longitudinal sections **48** control longitudinal strength and stability versus lateral flexibility. By adjusting these parameters, grafts can be made more or less flexible with greater or lesser anti-compression strength. In the preferred embodiment, four longitudinal sections **48** are formed and the ends of the structure **10** are completely encapsulated for greater stability. Of course, a larger number of longitudinal sections **48** could be formed. Also the longitudinal sections **48** may themselves zigzag or may be helically arranged depending on how the openings **44** are cut into the sleeve **42**. Each different structure will possess different properties. Similarly, the circumferential sections **46** can have different forms and may be undulating. There is nothing to preclude a covering with a more complex pattern where circumferential sections and longitudinal sections are difficult to discern or are even nonexistent.

[0016] A second embodiment of the present invention can be seen in Figs. 4-6. Instead of having a "lacey" graft structure, a slitted outer sleeve is used to provide partial encapsulation of the stent, the slits providing flexibility to the structure, allowing the stent to expand and retract more readily. In Fig. 4, four longitudinal slits **52** run the length of the stent, leaving 5 to 10mm of uncut sleeve at the ends. The slits are formed at 0°, 90°, 180°, and 270°, and are oriented to pass over a peak portion of each zigzag ring stent **30** (Fig. 6). Fig. 5 shows circumferential slits **62**, wherein slits are cut circumferentially around the sleeve **60** at spaced intervals, preferably to coincide with a stent ring. At each radial section, two slits are cut around the circumference at evenly spaced intervals. In a first radial section, the slits span from 0° to 90° and from 180° to 270°. Each successive radial section has a pair of slits which are offset 90° from the previous pair. Thus, a second radial section will have slits spanning from 90° to 180° and from 270° to 0°. Beside the configurations shown in Figs. 4 and 5, a number of other slit configurations are possible, including diagonal and sinusoidal as will be appreciated by one skilled in the art. As shown in Fig. 6, a sleeve **70** is placed over the ring stents **30** and the underlying tubular graft **20** to form a new structure **80**. The longitudinal slits **72**, which are cut into sleeve **70**, differ from the slits **52** shown in Fig. 4 in that they do not span the length of the structure **80** and are staggered around the circumference of the sleeve **70**. Ideally, the slits are aligned over the peaks in the zigzag ring stents **30**. Once the slits **72** are cut into the sleeve **70** using any of the known methods, the structure **80** is exposed to heat and pressure, such as that caused by wrapping with PTFE tape and heating in an oven, thereby causing the ePTFE regions of the slitted graft **70** to fuse or laminate to the tubular graft **20**. The slits **72** in the slitted outer sleeve **70** can be formed by using a CO_2 laser, razor blade or any other suitable technique known in the art. The slits enhance the flexibility of the encapsulated structure and allow radial expansion without tearing of the ePTFE. In addition, a plurality of slits help the expanded graft to grip onto the vessel wall. This is particularly important where an encapsulated stent graft is spanning a region of damaged or weakened vessel as in an aneurysm. Further, during the healing process tissues readily grow into the slits further anchoring the graft to the vessel wall.

[0017] An advantage that cutting slits into an ePTFE sleeve offers is that it is somewhat easier to manufacture than is the "lacey" graft. Because no material is removed the sleeve is somewhat stronger than a "lacey graft". There are a multitude of configurations possible, including cutting the slits in asymmetric fashion to achieve desired results, such as using radial, longitudinal and diagonal cuts simultaneously. Moreover, a greater number of slits can be cut into a region of the structure in which greater expansion is desired.

[0018] Although the above examples are described with the "lacey" and slitted grafts being placed over a stent which is itself placed over a tubular graft, this orientation can be readily reversed. That is, the "lacey" or slitted grafts can be placed on a mandrel; a stent or stents can be then placed over the "lacey" or slitted grafts, and a tubular graft can be then placed over the stent or stents. This results in a structure wherein part or much of the luminal surface is provided by the outer graft, resulting in superior healing as only a single layer of ePTFE would separate body tissues from the blood. Similarly, a structure with two "lacey" or slitted grafts is possible. By keeping the openings in one graft out of phase with those in the other graft a blood tight structure results. Nevertheless, a majority of the final surface area of the device would comprise a single layer separating body tissue from the circulating blood. Only the area actually occupied by the stent(s) and by overlap between the two grafts would present a barrier to cellular infiltration. Further such a structure would have a smaller profile when compressed because the overall amount of PTFE is reduced. Likewise, a combination of the "lacey" graft and slitted graft could be employed.

[0019] Zigzag stent rings have been illustrated, but it should be apparent that the inventive concepts described above would be equally applicable to sinusoidal and other stent designs. The described embodiments are to be considered illustrative rather than restrictive. The invention is further defined by the following claims.

Claims

1. A radially expandable reinforced vascular graft (10), comprising a first (20) and a second (40, 42, 50, 60, 70) expanded polytetrafluoroethylene layer and a radially expandable support layer comprising at

least one stent (30), wherein the support layer (30) is in contact with a surface of the first expanded polytetrafluoroethylene layer (20) and is secured thereto by the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70), ***characterized in that*** at least one of the expanded polytetrafluoroethylene layers (20, 40, 42, 50, 60, 70) includes a plurality of spaced apart apertures (44, 52, 62, 72) cut directly therein, adapted to leave at least a portion of the support layer unsecured.

2. The radially expandable reinforced vascular graft (10) according to claim 1, wherein the second expanded polytetrafluoroethylene layer (40,42,50,60,70) includes said plurality of spaced apart apertures.

3. The radially expandable reinforced vascular graft according to claim 1, wherein both the first and second expanded polytetrafluoroethylene layers (20, 40, 42, 50, 60, 70) include a plurality of spaced apart apertures (44, 52, 62, 72) wherein the apertures in the first expanded polytetrafluoroethylene layer (20) are adapted to be aligned out of phase with the apertures in the second expanded polytetrafluoroethylene layer.

4. A radially expandable reinforced vascular graft as in any one of the preceding claims, wherein the apertures further comprise slits (52, 62, 72).

5. The radially expandable reinforced vascular graft according to claim 3, wherein the apertures in the first (20) or second (40) expanded polytetrafluoroethylene layer further comprise slits.

6. A radially expandable reinforced vascular graft as in claims 4 or 5, wherein the slits (52, 72) are oriented longitudinally.

7. The radially expandable reinforced vascular graft as in claims 4 or 5, wherein the slits (62) are oriented circumferentially.

8. A radially expandable reinforced vascular graft as in any of the preceding claims, wherein the radially expandable support layer comprises a plurality of ring stents (30).

9. The radially expandable reinforced vascular graft according to claim 8, wherein each of the ring stents (30) is formed in a zigzag pattern of alternating peaks and valleys.

10. The radially expandable reinforced vascular graft according to claim 9, wherein the zigzag ring stents (30) are adapted to be aligned with the alternating peaks and valleys in phase.

11. The radially expandable reinforced vascular graft as in any of the preceding claims, wherein the stent is made of metal.

12. The radially expandable reinforced vascular graft as in any of the preceding claims, wherein at least one end of the radially expandable reinforced vascular graft is fully encapsulated.

13. A method for making a partially encapsulated radially expandable reinforced vascular graft (10), comprising providing a first expanded polytetrafluoroethylene layer of material (20), providing a second expanded polytetrafluoroethylene layer of material (40, 42, 50, 60, 70), disposing a radially expandable support layer comprising at least one stent (30) over the first expanded polytetrafluoroethylene layer, placing the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) over the radially expandable support layer (30), and laminating the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) to the first expanded polytetrafluoroethylene layer, ***characterized by*** cutting a plurality of apertures (44, 52, 62, 72) into at least one of the expanded polytetrafluoroethylene layers (20, 40, 42, 50, 60, 70) and positioning the apertures (44, 52, 62, 72) with respect to the support layer, leaving a portion of the support layer exposed through the apertures.

14. The method according to claim 13, wherein the radially expandable support layer comprises a plurality of ring stents (30) formed in a zigzag pattern of alternating peaks and valleys, wherein the disposing step further comprises disposing the peaks and valleys of successive stents in phase.

15. The method as in claims 13 or 14, further comprising the step of fully encapsulating at least one end of the radially expandable reinforced vascular graft.

16. A method for making a partially encapsulated radially expandable reinforced vascular graft, comprising providing a first expanded polytetrafluoroethylene layer of material (20), providing a second expanded polytetrafluoroethylene layer of material (40), disposing a radially expandable support layer comprising at least one stent (30) over the first expanded polytetrafluoroethylene layer (20), placing the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) over the radially expandable support layer (30), and laminating the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) to the first expanded polytetrafluoroethylene layer (20), ***characterized by*** cutting a plurality of slits (52, 62, 72) into at least one of the tubular expanded polytetrafluoroethylene layers (50, 60, 70) and positioning the slits (52, 62, 72) to span at least

a portion of the radially expandable support layer.

17. The method according to claim 16, wherein the radially expandable support layer comprises a plurality of ring stents (30) formed in a zigzag pattern of alternating peaks and valleys, wherein the disposing step further comprises disposing said peaks and valleys of successive stents in phase.

18. The method as in claims 16 or 17, further comprising the step of fully encapsulating at least one end of the radially expandable reinforced vascular graft.

Patentansprüche

1. Radial ausdehnbares verstärktes Gefäßtransplantat (10) mit einer ersten (20) und einer zweiten (40, 42, 50, 60, 70) ausgedehnten Polytetrafluorethylenschicht und einer radial ausdehnbaren Stützschicht, die zumindest einen Stent (30) aufweist, wobei die Stützschicht (30) in Kontakt mit einer Oberfläche der ersten ausgedehnten Polytetrafluorethylenschicht (20) ist und darin mittels der zweiten ausgedehnten Polytetrafluorethylenschicht (20, 40, 42, 50, 60, 70) befestigt ist, ***dadurch gekennzeichnet, dass*** zumindest eine der ausgedehnten Polytetrafluorethylenschichten (20, 40, 42, 50, 60, 70) mehrere beabstandete Öffnungen (44, 52, 62, 72) beinhaltet, die direkt dort hineingeschnitten sind und dazu angepasst sind, zumindest einen Bereich der Stützschicht unbefestigt zu lassen.

2. Radial ausdehnbares verstärktes Gefäßtransplantat (10) nach Anspruch 1, wobei die zweite ausgedehnte Polytetrafluorethylenschicht (40, 42, 50, 60, 70) die mehreren beabstandeten Öffnungen beinhaltet.

3. Radial ausdehnbares verstärktes Gefäßtransplantat (10) nach Anspruch 1, wobei die sowohl die erste als auch die zweite ausgedehnte Polytetrafluorethylenschicht (20, 40, 42, 50, 60, 70) mehrere beabstandete Öffnungen (44, 52, 62, 72) aufweisen, wobei die Öffnungen in der ersten ausgedehnten Polytetrafluorethylenschicht (20) dazu angepasst sind, außer Phase mit den Öffnungen in der zweiten ausgedehnten Polytetrafluorethylenschicht ausgerichtet zu sein.

4. Radial ausdehnbares verstärktes Gefäßtransplantat nach einem der vorangehenden Ansprüche, wobei die Öffnungen außerdem aus Schlitzen (52, 62, 72) bestehen.

5. Radial ausdehnbares verstärktes Gefäßtransplantat nach Anspruch 3, wobei die Öffnungen in der ersten (20) oder der zweiten (40) ausgedehnten Polytetrafluorethylenschicht außerdem aus Schlitzen bestehen.

6. Radial ausdehnbares verstärktes Gefäßtransplantat nach Anspruch 4 oder 5, wobei die Schlitze (52, 72) in Längsrichtung orientiert sind.

7. Radial ausdehnbares verstärktes Gefäßtransplantat nach Anspruch 4 oder 5, wobei die Schlitze (62) in Umfangsrichtung orientiert sind.

8. Radial ausdehnbares verstärktes Gefäßtransplantat nach einem der vorangehenden Ansprüche, wobei die radial ausdehnbare Stützschicht mehrere Ringstents (30) beinhaltet.

9. Radial ausdehnbares verstärktes Gefäßtransplantat nach Anspruch 8, wobei jeder der Ringstents (30) in einem Zick-Zack-Muster aus sich abwechselnden Spitzen und Tälern ausgeformt ist.

10. Radial ausdehnbares verstärktes Gefäßtransplantat nach Anspruch 9, wobei die Zick-Zack-Ringstents (30) dazu angepasst sind, mit den abwechselnden Spitzen und Tälern in Phase ausgerichtet zu sein.

11. Radial ausdehnbares verstärktes Gefäßtransplantat nach einem der vorangehenden Ansprüche, wobei der Stent aus Metall besteht.

12. Radial ausdehnbares verstärktes Gefäßtransplantat nach einem der vorangehenden Ansprüche, wobei zumindest ein Ende des radial ausdehnbaren verstärkten Gefäßimplantats vollständig eingekapselt ist.

13. Verfahren zur Herstellung eines teilweise eingekapselten radial ausdehnbaren verstärkten Gefäßimplantats (10), mit den folgenden Schritten: Vorsehen einer ersten ausgedehnten Polytetrafluorethylenschicht aus Material (20), Vorsehen einer zweiten ausgedehnten Polytetrafluorethylenschicht aus Material (40, 42, 50, 60, 70), 20), Anordnen einer radial ausdehnbaren Stützschicht, die zumindest einen Stent (30) einschließt, über der ersten ausgedehnten Polytetrafluorethylenschicht, Platzieren der zweiten ausgedehnten Polytetrafluorethylenschicht (40, 42, 50, 60, 70) über der radial ausdehnbaren Stützschicht (30), und Laminieren der zweiten ausgedehnten Polytetrafluorethylenschicht (40, 42, 50, 60, 70) auf die erste ausgedehnte Polytetrafluorethylenschicht, ***gekennzeichnet durch:*** das Schneiden von mehreren Öffnungen (44, 52, 62, 72) in zumindest eine der ausgedehnten Polytetrafluorethylenschichten (20, 40, 42, 50, 60, 70) und das Positionieren der Öffnungen (44, 52, 62, 72) der Stützschicht, wobei ein Bereich der Stütz-

schicht **durch** die Öffnungen hindurch freiliegend gelassen wird.

14. Verfahren nach Anspruch 13, wobei die radial ausdehnbare Stützschicht mehrere Ringstents (30) aufweist, die in einem Zick-Zack-Muster aus sich abwechselnden Tälern und Spitzen ausgeformt sind, wobei der Schritt des Anordnens außerdem das Anordnen der Täler und Spitzen von aufeinanderfolgenden Stents in Phase beinhaltet.

15. Verfahren nach Anspruch 13 oder 14, weiter mit dem Schritt des vollständigen Einkapselns zumindest eines Endes des radial ausdehnbaren verstärkten Gefäßimplantats.

16. Verfahren zur Herstellung eines teilweise eingekapselten radial ausdehnbaren, verstärkten Gefäßimplantats (10), mit den folgenden Schritten: Vorsehen einer ersten ausgedehnten Polytetrafluorethylenschicht aus Material (20), Vorsehen einer zweiten ausgedehnten Polytetrafluorethylenschicht aus Material (40, 42, 50, 60, 70), 20), Anordnen einer radial ausdehnbaren Stützschicht, die zumindest einen Stent (30) einschließt, über der ersten ausgedehnten Polytetrafluorethylenschicht, Platzieren der zweiten ausgedehnten Polytetrafluorethylenschicht (40, 42, 50, 60, 70) über der radial ausdehnbaren Stützschicht (30), und Laminieren der zweiten ausgedehnten Polytetrafluorethylenschicht (40, 42, 50, 60, 70) auf die erste ausgedehnte Polytetrafluorethylenschicht, ***gekennzeichnet durch:*** das Schneiden von mehreren Schlitzen (52, 62, 72) in zumindest eine der röhrenförmigen ausgedehnten Polytetrafluorethylenschichten (50, 60, 70) und Positionieren der Schlitze (52, 62, 72), so dass sie zumindest einen Bereich der radial ausdehnbaren Stützschicht überspannen.

17. Verfahren nach Anspruch 16, wobei die radial ausdehnbare Stützschicht mehrere Ringstents (30) aufweist, die in einem Zick-Zack-Muster aus sich abwechselnden Spitzen und Tälern ausgeformt sind, wobei der Schritt des Anordnens außerdem das Anordnen der Spitzen und Täler von aufeinanderfolgenden Stents in Phase aufweist.

18. Verfahren nach Anspruch 16 oder 17, weiter mit dem Schritt des vollständigen Einkapselns zumindest eines Endes des radial ausdehnbaren verstärkten Gefäßimplantats.

Revendications

1. Greffe vasculaire renforcée dilatable de façon radiale (10), comprenant une première (20) et une seconde (40, 42, 50, 60, 70) couche de polytétrafluoroéthylène expansé et une couche de support dilatable de façon radiale comprenant au moins un stent (30), dans laquelle la couche de support (30) est en contact avec une surface de la première couche de polytétrafluoroéthylène expansé (20) et est fixée à celle-ci par la seconde couche de polytétrafluoroéthylène expansé (40, 42, 50, 60, 70), **caractérisée en ce qu'**au moins l'une des couches de polytétrafluoroéthylène expansé (20, 40, 42, 50, 60, 70) contient une pluralité d'ouvertures espacées (44, 52, 62, 72) directement coupées dans celle-ci, adaptées pour laisser au moins une partie de la couche de support non fixée.

2. Greffe vasculaire renforcée dilatable de façon radiale (10) selon la revendication 1, dans laquelle la seconde couche de polytétrafluoroéthylène expansé (40, 42, 50, 60, 70) inclut ladite pluralité d'ouvertures espacées.

3. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 1, dans laquelle la première et la seconde couches (20, 40, 42, 50, 60, 70) de polytétrafluoroéthylène expansé contiennent une pluralité d'ouvertures espacées (44, 52, 62, 72), dans laquelle les ouvertures dans la première couche de polytétrafluoroéthylène expansé (20) sont adaptées pour être alignées en décalage avec les ouvertures dans la seconde couche de polytétrafluoroéthylène expansé.

4. Greffe vasculaire renforcée dilatable de façon radiale selon l'une quelconque des revendications précédentes, dans laquelle les ouvertures comprennent en plus des fentes (52, 62, 72).

5. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 3, dans laquelle les ouvertures dans la première (20) ou la seconde (40) couche de polytétrafluoroéthylène expansé comprend en plus des fentes.

6. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 4 ou 5, dans laquelle les fentes (52, 72) sont orientées de façon longitudinale.

7. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 4 ou 5, dans laquelle les fentes (62) sont orientées de façon circonférentielle.

8. Greffe vasculaire renforcée dilatable de façon radiale selon l'une quelconque des revendications précédentes, dans laquelle la couche de support dilatable de façon radiale comprend une pluralité de stents circulaires (30).

9. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 8, dans laquelle chacun des stents circulaires (30) est formé selon un motif en zigzag d'alternance de pics et de vallées.

10. Greffe vasculaire renforcée dilatable de façon radiale selon la revendication 9, dans laquelle les stents circulaires en zigzag (30) sont adaptés pour être alignés en phase avec les alternances de pics et de vallées.

11. Greffe vasculaire renforcée dilatable de façon radiale selon l'une quelconque des revendications précédentes, dans laquelle le stent est en métal.

12. Greffe vasculaire renforcée dilatable de façon radiale selon l'une quelconque des revendications précédentes, dans laquelle au moins une extrémité de la greffe vasculaire renforcée dilatable de façon radiale est complètement encapsulée.

13. Procédé de fabrication d'une greffe vasculaire renforcée dilatable de façon radiale (10) partiellement encapsulée, comprenant les étapes consistant à fournir une première couche de matériau en polytétrafluoroéthylène expansé (20), à fournir une seconde couche de matériau en polytétrafluoroéthylène expansé (40, 42, 50, 60, 70), à disposer une couche de support dilatable de façon radiale comprenant au moins un stent (30) sur la première couche en polytétrafluoroéthylène expansé, à placer la seconde couche en polytétrafluoroéthylène expansé (40, 42, 50, 60, 70) sur la couche de support dilatable de façon radiale (30), et à laminer la seconde couche en polytétrafluoroéthylène expansé (40, 42, 50, 60, 70) à la première couche en polytétrafluoroéthylène expansé, **caractérisé par** les étapes consistant à couper une pluralité d'ouvertures (44, 52, 62, 72) dans au moins l'une des couches en polytétrafluoroéthylène expansé (20, 40, 42, 50, 60, 70) et à positionner les ouvertures (44, 52, 62 72) par rapport à la couche de support, en laissant une partie de la couche de support exposée au travers des ouvertures.

14. Procédé selon la revendication 13, dans lequel la couche de support dilatable de façon radiale comprend une pluralité de stents circulaires (30) formés selon un motif en zigzag d'alternances de pics et de vallées, dans lequel l'étape de disposition comprend en plus le fait de disposer en phase les pics et les vallées des stents successifs.

15. Procédé selon la revendication 13 ou 14, comprenant en plus l'étape d'encapsulation totale d'au moins une extrémité de la greffe vasculaire renforcée dilatable de façon radiale.

16. Procédé de fabrication d'une greffe vasculaire renforcée dilatable de façon radiale partiellement encapsulée, comprenant les étapes consistant à fournir une première couche de matériau en polytétrafluoroéthylène expansé (20), à fournir une seconde couche de matériau en polytétrafluoroéthylène expansé (40), à disposer une couche de support dilatable de façon radiale comprenant au moins un stent (30) sur la première couche en polytétrafluoroéthylène expansé (20), à placer la seconde couche en polytétrafluoroéthylène expansé (40, 42, 50, 60, 70) sur la couche de support dilatable de façon radiale (30), et à laminer la seconde couche en polytétrafluoroéthylène expansé (40, 42, 50, 60, 70) à la première couche en polytétrafluoroéthylène expansé (20), **caractérisé par** le fait de couper une pluralité de fentes (52, 62, 72) dans au moins une des couches tubulaires en polytétrafluoroéthylène expansé (50, 60, 70) et le fait de positionner les fentes (52, 62, 72) pour relier au moins une partie de la couche de support dilatable de façon radiale.

17. Procédé selon la revendication 16, dans lequel la couche de support dilatable de façon radiale comprend une pluralité de stents circulaires (30) formés selon un motif en zigzag d'alternance de pics et de vallées, dans lequel l'étape de disposition comprend en plus le fait de disposer en phase lesdits pics et vallées des stents successifs.

18. Procédé selon l'une des revendications 16 ou 17, comprenant en plus l'étape d'encapsulation totale d'au moins une extrémité de la greffe vasculaire renforcée dilatable de façon radiale.

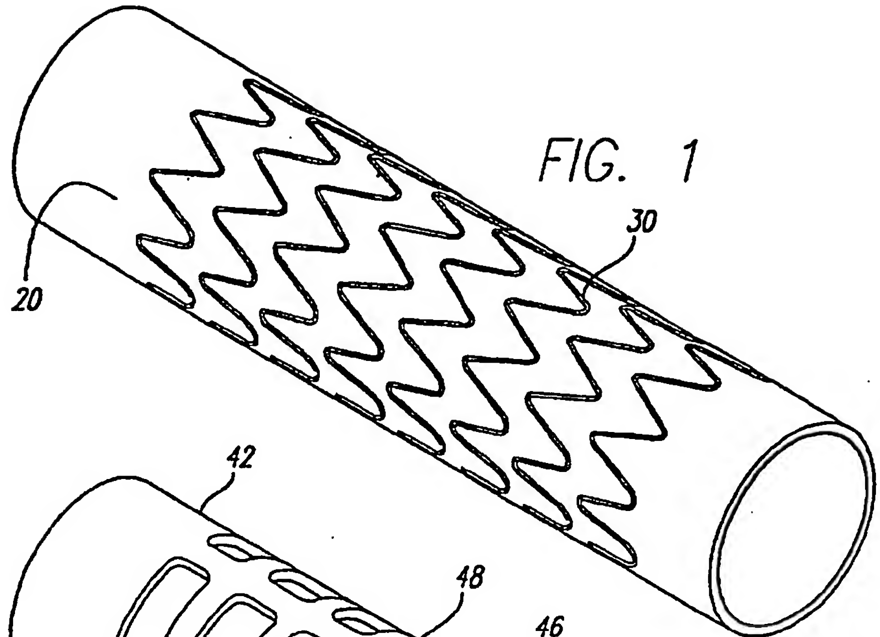

FIG. 1

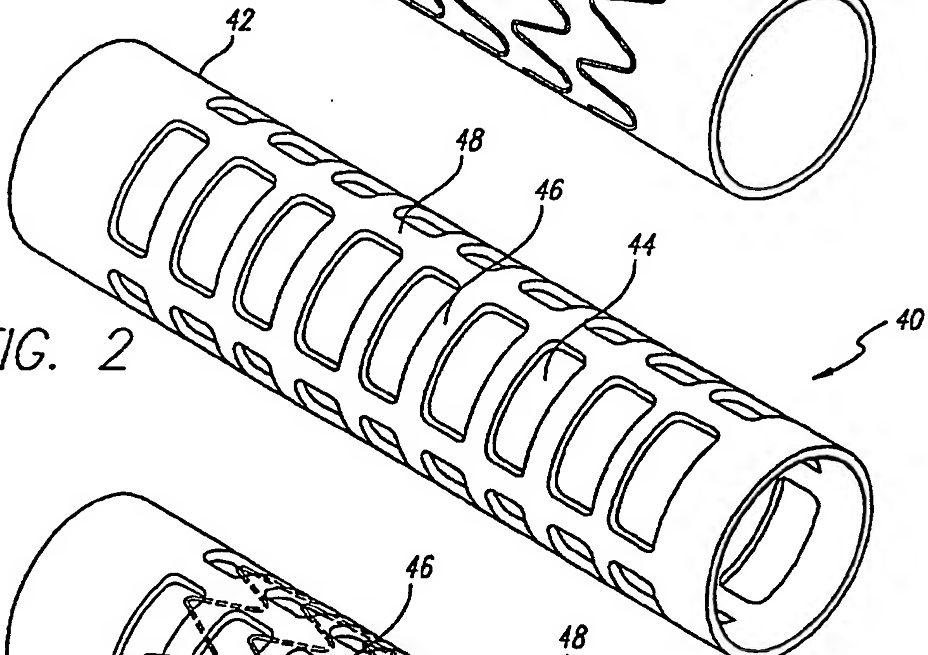

FIG. 2

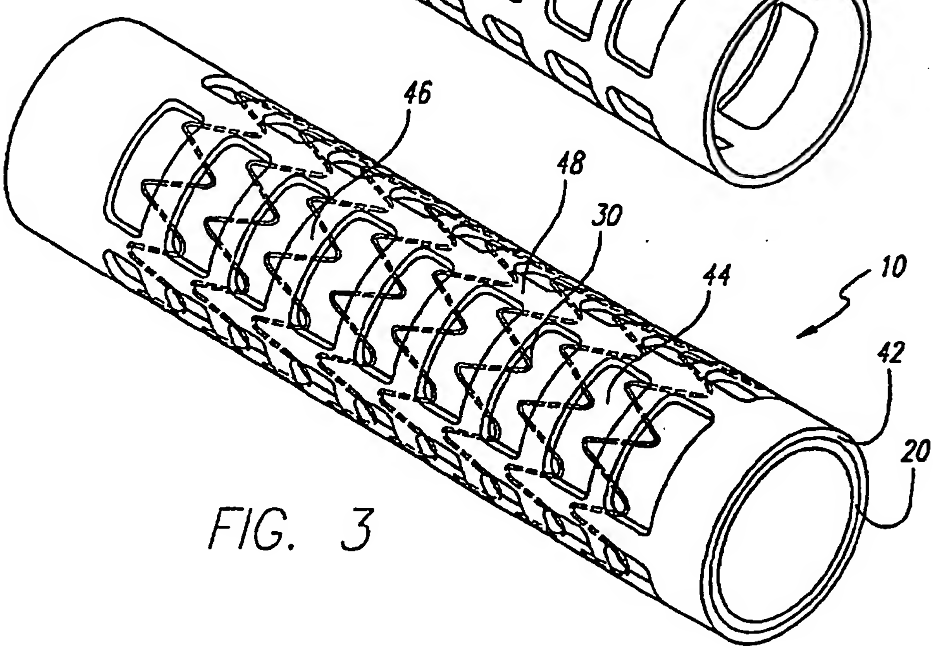

FIG. 3

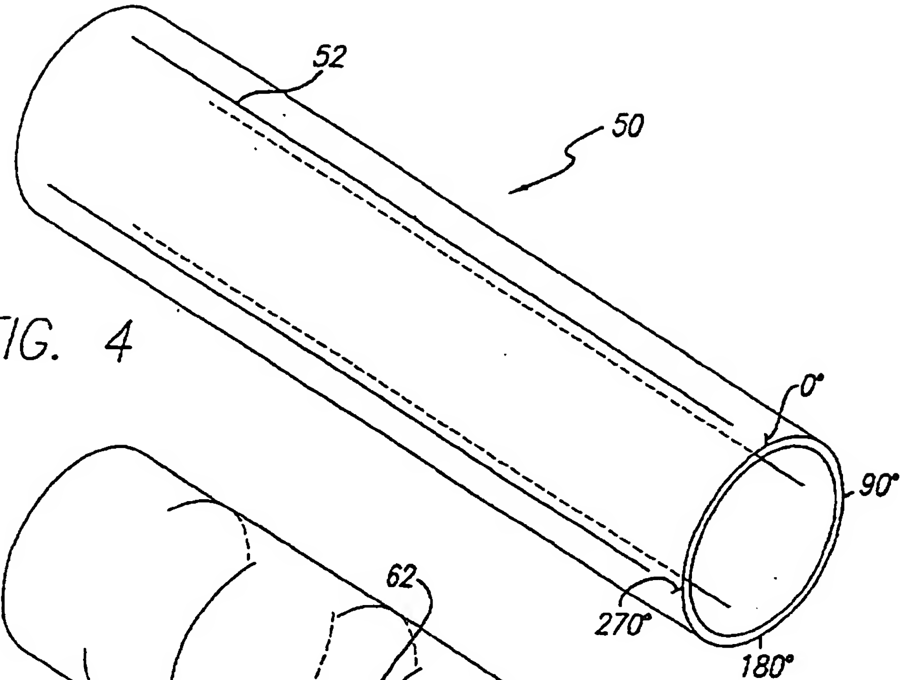

FIG. 4

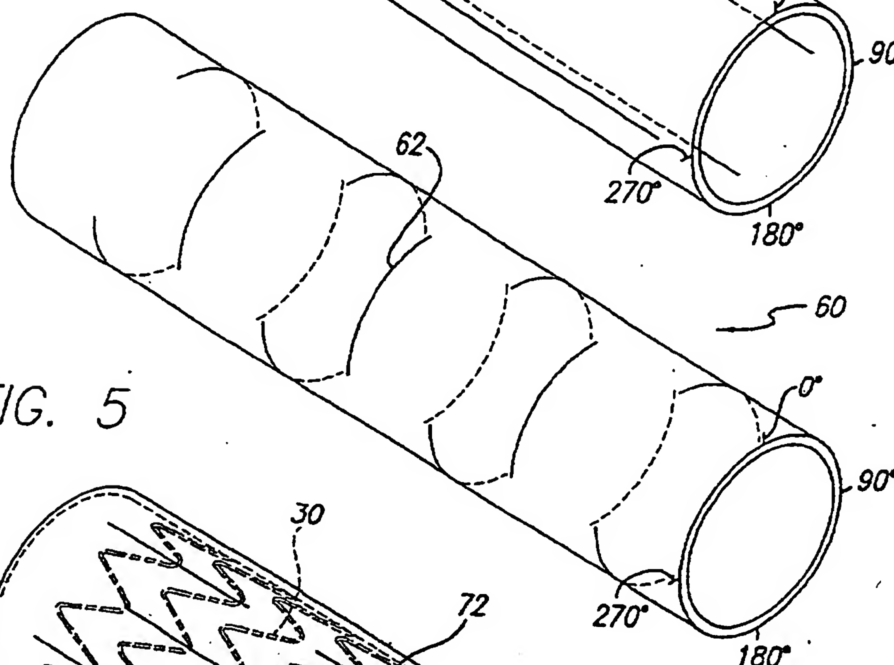

FIG. 5

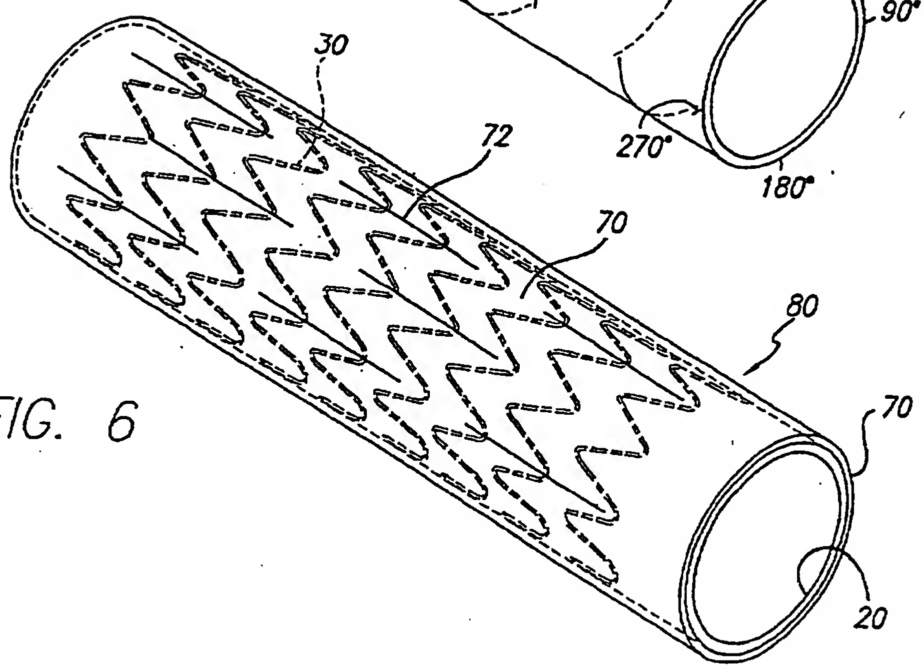

FIG. 6